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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SHIAO, REI TSANG

ART UNIT	PAPER NUMBER
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1626

MAIL DATE	DELIVERY MODE
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01/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/551,200

Applicant(s)

WEST ET AL.

Examiner

REI-TSANG SHIAO

Art Unit

1626

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-17 and 23-32 is/are pending in the application.
- 4a) Of the above claim(s) 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-17, 23, 24 and 26-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date 12/16/08, 8/31/06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This application claims benefit of the foreign application:
AUSTRALIA 2003901815 with a filing date 04/15/2003.
2. Amendment of claim 3-6, 9-10, 12-14, 17 and 23-25, cancellation of claims 2 and 18-22, and addition of claims 26-32 in the amendment filed on November 26, 2008 is acknowledged. Claims 1, 3-17 and 23-32 are pending in the application. No new matter has been found. Since the newly added claims 26-32 are commensurate within the scope of invention, claims 1, 3-17 and 23-32 are prosecuted in the case.

Information Disclosure Statement

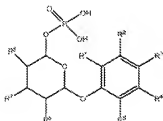
3. Applicant's Information Disclosure Statements filed on December 16, 2008, and August 31, 2006 have been considered. Please refer to Applicant's copies of the 1449's submitted herein.

Responses to Election/Restriction

4. Applicant's election with traverse of election of Group II claims 1-17 and 23-24, in part (now are 1, 3-17 and 23-24, in part), in the reply filed on November 26, 2008 is acknowledged. Election of the compound of Example 1, i.e., 2-(2,6-diisopropylphenoxy)-tetrahydropyrano-6-yl, dihydrogen phosphate, as the single species is also acknowledged. The traversal is on the grounds that the Examiner expand the search to cover the broader genus. This is found not persuasive, and the reasons are given *infra*.

Claims 1, 3-17 and 23-32 are pending in the application. The scope of the invention of the elected subject matter is as follows.

Claims 1, 3-17 and 23-24, in part, drawn to phosphate derivative compounds of phenolic hydroxyl compounds of formula (II) thereof, i.e.,



The claims 1, 3-17 and 23-32 herein lack unity of invention under PCT rule 13.1 and 13.2 since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art, see *Pla i Rodas et al.* CAS: 108:186992. *Pla i Rodas et al.* disclose similar phosphate derivative compounds of formula (I). Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Furthermore, even if unity of invention under 37 CFR 1.475(a) is not lacking, which it is lacking, under 37 CFR 1.475(b) a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations:

- (1) A product and a process specially adapted for the manufacture of said product', or
- (2) A product and a process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

And, according to 37 CFR 1.475(c)

if an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

However, it is noted that unity of invention is considered lacking under 37 CFR 1.475(a) and (b). Therefore, since the claims are drawn to more than a product, and according to 37 CFR 1.475 (e)

the determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

The claims lack unity of invention and should be limited to only a product, or a process for the preparation, or a use of the said product. In the instant case, Groups I-V are drawn to various products (i.e., formulae (I) –(II), etc), processes of making, and the final products do not contain a common technical feature or structure, and do not define a contribution over the prior art, i.e., similar phosphate derivative compounds of Pla i Rodas et al. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner.

Claims 1, 3-17, 23-24 and 26-32, in part, embraced in above elected subject matter, are prosecuted in the case. Claims 1, 3-17, 23-24 and 26-32, in part, not embraced in

above elected subject matter, and 25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper and is therefor made FINAL.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-17, 23-24 and 26-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the instant phosphate derivative compounds of phenolic hydroxyl compounds of formula (II), does not reasonably provide enablement for phosphate derivative compounds phenolic hydroxyl compounds of or their prodrugs without limitation (i.e., no named compounds or no formula), see claim 1 or 23. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,

3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case:

The nature of the invention

The nature of the invention is a phosphate derivative compounds of phenolic hydroxyl compounds or their prodrugs without limitation (i.e., no named compounds or no formula), see claim 1 and 23.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is Pla i Rodas et al. CAS: 108:186992, it discloses similar phosphate compounds.

The amount of direction or guidance present and the presence or absence of working examples

The only direction or guidance present in the instant specification is the phosphate derivative compounds of phenolic hydroxyl compounds representing compounds of formula (II), see pages 4-5 of the specification. There is no data present

in the instant phosphate derivative compounds of phenolic hydroxyl compounds or their prodrugs, which are not limited.

The breadth of the claims

The instant breadth of the rejected claims is broader than the disclosure, specifically, the instant claims include any phosphate derivative compounds of phenolic hydroxyl compounds and their derivatives, which are not limited.

The quantity or experimentation needed and the level of skill in the art

While the level of the skill in the chemical arts is high, it would require undue experimentation of one of ordinary skill in the art to resolve any phosphate derivative compounds of phenolic hydroxyl compounds and their derivatives, which are not limited. There is no guidance or working examples present for constitutional any phosphate derivative compounds of phenolic hydroxyl compounds and their prodrugs, which are not limited. Incorporation of the limitation of the limitation of phosphate derivative compounds of phenolic hydroxyl compounds (i.e., formula (II)) into claim 1, and deletion of the limitation "prodrug", would overcome this rejection. Dependent claims 3-17, 23-24 and 26-32 are also rejected along with claim 1 under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-17, 23-24 and 26-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 23 respectively recite the limitation "comprising", is indefinite and ambiguous, i.e., see line 1 of claim 1. It is recited as a compound claim and use the term "comprising" which is open-ended, a compound claim cannot use open-ended language when defining the parameters of the compound, see M.P.E.P. 2111.03. By deleting "comprising" and inserting a term "consisting of" the rejection would be overcome.

Claims 4, 6-8 and 12-16 recites the limitation "a complexing agent", i.e., see lines 2-3 in claim 4. There is insufficient antecedent basis for this limitation in the claim.

Claims 6 and 12 and 14 respectively recite the limitation "R9 is R9(CO)", is indefinite and ambiguous, i.e., see line 13 of claim 6. It is unclear what the limitation of the variable R9 is. The limitation "R9 is R9(CO)" is not found in the original scope of the variable R9. Dependent claims 3-17, 23-24 and 26-32 are also rejected along with claim 1 under 35 U.S.C. 112, second paragraph.

Claims Objection

7. Claims 1, 3-17, 23-24 and 26-32 are objected to as containing non-elected subject matter, i.e., phosphate derivative compounds of phenolic hydroxyl compounds

other than formula (II), etc. It is suggested that applicants amend the claims to the scope of the elected subject matter as defined on the pages 2-3 *supra*.

8. Claim 24 is objected to for being substantial duplicates of the claims from which they depend, i.e., claim 3. When two claims in an application are duplicates, or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to reject the other as being a substantial duplicate of the allowed claim. M.P.E.P. 706.03(k).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rei-tsang Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

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Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/REI-TSANG SHIAO /

Rei-tsang Shiao, Ph.D.
Primary Examiner
Art Unit 1626

January 22, 2009